

Attorney Docket No.: ARC 2556 N1

IN THE CLAIMS:

Please amend claims 12 through 15, 18 and 24 as set forth below. Please cancel claims 16 and 19 through 23 without prejudice or disclaimer. Applicants note that all claims currently pending in the application are shown below for clarity.

Claim 12 (Currently Amended): A sustained-release dosage form for the delivery of a progestogenic steroid, the dosage form comprising:

a capsule;

a self-emulsifying drug formulation contained within a capsule, wherein [the dosage form is configured to expel the self-emulsifying drug formulation from the capsule at a sustained rate after introduction of the dosage form to an environment of operation] the self-emulsifying drug formulation comprises a progestogenic steroid;

an expandable layer positioned such that the self-emulsifying drug formulation can be expelled from the capsule upon expansion of the expandable layer;

a semipermeable membrane formed over at least a portion of an outer surface of the capsule.

Claim 13 (Currently Amended): The dosage form of claim 12, [further comprising an expandable layer formed of] wherein the expandable layer comprises an osmotic hydrogel, an osmotically effective solute, and a hydroxyalkylcellulose[, wherein the expandable layer is positioned such that the self-emulsifying drug formulation can be expelled from the capsule upon expansion of the expandable layer].

Claim 14 (Currently Amended): The dosage form of claim 12, [wherein the capsule comprises an inner surface and an outer surface and a semipermeable membrane is formed over at least a portion of the outer surface of the capsule, the semipermeable membrane being created such that] further comprising an exit orifice that is formed or formable [therein] within the

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semipermeable membrane.

Claim 15 (Currently Amended): The dosage form of claim [14] 12, wherein the semipermeable membrane comprises a cellulose acetate and a polyethylene glycol.

Please cancel claim 16 without prejudice or disclaimer.

Claim 17 (Previously Amended): The dosage form of claim 12, wherein the self-emulsifying drug formulation comprises a surfactant selected from the group consisting of polyoxyethylenated castor oil comprising 9 moles to 52 moles of ethylene oxide, polyoxyethylenated sorbitan monopalmitate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 4 moles of ethylene oxide, polyoxyethylenated sorbitan tristearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan trioleate comprising 20 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 8 moles of ethylene oxide, polyoxyethylene lauryl ether, polyoxyethylenated stearic acid comprising 40 moles to 50 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 50 moles of ethylene oxide, polyoxyethylenated stearyl alcohol comprising 2 moles of ethylene oxide, and polyoxyethylenated oleyl alcohol comprising 2 moles of ethylene oxide.

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Claim 18 (Currently Amended): [A sustained-release] The dosage form [comprising:  
a) of claim 12, wherein the self-emulsifying drug formulation [comprising a drug, a  
surfactant, and] comprises an oil selected from the group consisting of a vegetable, mineral,  
animal and marine oil, an ester of an unsaturated fatty acid, a monoglyceride, a diglyceride, a  
triglyceride, an acetylated glyceride, olein, palmitin, stearin, lauric acid hexylester, oleic acid,  
oleylester, glycolized ethoxylated glycerides of oils, fatty acids comprising 13 molecules of  
ethyleneoxide, and oleic acid decylester]; and

a capsule containing the self-emulsifying formulation, wherein the dosage form is  
configured to expel the self-emulsifying drug formulation from the capsule at a sustained rate  
after introduction of the dosage form to an environment of operation].

Please cancel claims 19 through 23 without prejudice or disclaimer.

Claim 24 (Currently Amended): The dosage form of claim [20] 12, wherein the  
semipermeable membrane comprises a thermoplastic polymer composition having a softening  
point of 40°C to 180°C.

#### **REMARKS**

The Office Action mailed March 17, 2002 (hereinafter the Office Action), has been  
received and reviewed. Claims 12 through 24 are currently pending in the application, and  
claims 12 through 24 stand rejected. Applicants, however, have herein amended claims 12  
through 15, 18, and 24, and Applicants respectfully request reconsideration of the application in  
light of the remarks set forth herein.

#### **Rejections Under 35 U.S.C. § 112**

Claims 12-24 stand rejected under 35 U.S.C. § 112, first paragraph. It is asserted in the  
Office Action that the claims contain "subject matter which was not described in the